

skilled in the relevant art that the inventors, at the time of invention, had possession of the claimed invention. The Examiner also rejected claims 20-33 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner rejected claims 1, 3-5, 7, 9, 20, 23-25, 27, 29, 45-49, and 53 under 35 U.S.C. § 102(e) as being anticipated by Hamblin, Jr. et al. United States Patent No. 6,197,054 (hereinafter Hamblin), Magovern et al. United States Patent No. 6,016,550 (hereinafter Magovern), and Bessler et al. United States Patent No. 5,855,601 (hereinafter Bessler).

Summary of the Reply

Applicants have provided a list of claims and support in the specification readable on the elected species as required by the Examiner.

Applicants have submitted that claim 51 was mistakenly¹ withdrawn by the Examiner and have requested initial substantive examination of claim 51.

Applicants have amended claims 1, 20, and 45 and deleted claims 10, 30, and 54 to more clearly define the limitations of the present invention. These amendments contain no new matter. Applicants have used these

amendments in support of arguments for the traversal of the Examiner's rejections of claims 1, 3-5, 7, 9, 20, 23-25, 27, 29, 45-49, and 53 under 35 U.S.C. § 102 and 35 U.S.C. § 112. Applicants' remarks are set forth below in detail.

Applicants' Reply to the
Election Requirement

The Examiner noted that Applicants failed to provide a listing of claims readable on the elected species. Accordingly, the Examiner required applicants to provide a list of claims that read on the elected embodiment shown in FIG. 7 and show where support for the claims is found in the specification. The required lists of the claims readable on the elected species and the references to show support in the specification are set forth in the table below.

CLAIM NO.	SUPPORT IN SPECIFICATION
1	page 9, lines 3-8
3	page 9, lines 22-29
4	page 9, line 16
5	page 6, paragraph beginning at line 34
7	page 11, paragraph beginning at line 33
9	page 9, lines 5-8
20	page 3, lines 5-13
23	page 9, lines 22-29
24	page 9, line 16
25	page 6, paragraph beginning at line 34
27	page 11, paragraph beginning at line 33
29	page 9, lines 5-8
45	page 3, lines 19-21
46	page 3, lines 12-13
47	page 9, lines 22-29
48	page 9, line 16

49	page 6, paragraph beginning at line 34
51	page 11, paragraph beginning at line 33
53	page 9, lines 5-8

Applicants note, with appreciation, the Examiner's interest in expediting the application. However, applicants respectfully submit that the Examiner has mistakenly withdrawn claim 51. Claim 51, dependent from independent claim 45, is related to barbed fingers. The Examiner did not withdraw claims 7 and 27, dependent from independent claims 1 and 20 respectively, which are both related to barbed fingers as well. Applicants do not see a reason for allowing the fingers to be barbed in claims 7 and 27 but not allowing the fingers to be barbed in claim 51. Accordingly, applicants respectfully request substantive examination of claim 51. Nevertheless, in the interest of expediting prosecution, applicants are prepared to submit to the Examiner's withdrawal of claim 51 and to pursue claim 51 in a divisional application if the Examiner so requires.

Applicants' Reply to the
Rejections Under 35 U.S.C. § 112

First Paragraph

The Examiner rejected claims 1, 20, 45 and their dependent claims under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner stated that claim 45 and FIG. 7 are unclear as to how the fingers are connected to the heart valve. The Examiner's rejection is respectfully traversed.

The Examiner questioned whether the fingers in the elected embodiment are attached directly to the body of the heart valve or indirectly via a band. Claim 45 clearly states that the valve apparatus includes a plurality of fingers, located circumferentially around, and attached to the valve. Furthermore, attachment of fingers directly to a valve is well supported in the specification. For example, the Summary of the Invention states, ". . . fingers can be implemented on the valve itself, thereby obviating the need for a connector band," (see page 3, lines 19-21).

The Examiner also stated that claim 45 does not claim a band as required in claim 1. However, applicants submit that claim 45 need not have the same elements as claim 1. Pursuant to 37 C.F.R. § 1.75, applicants may present more than one claim "provided they differ substantially from each other." Applicants submit that claim 45, by not requiring a band element, is substantially different from claim 1 and that the specification fully

supports embodiments with a band and embodiments without a band.

In view of the foregoing arguments, applicants respectfully request that the Examiner's rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Second Paragraph

The Examiner rejected claims 20-33 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Examiner referred to claim 20, suggesting ambiguities with "the plurality of recesses for receiving the valve," (see the December 3, 2001 Office Action, page 2). Applicants have amended claim 20 to more clearly point out and distinctly claim the invention by deleting the reference to a plurality of recesses. No new matter has been added. The Examiner's rejection under 35 U.S.C. § 112, first paragraph, is respectfully traversed.

Applicants' Reply to the
Rejections Under 35 U.S.C. § 102(e)

The Examiner rejected claims 1, 3-5, 7, 9, 20, 23-25, 27, 29, 45-49, and 53 under 35 U.S.C. § 102(e) as being anticipated by Hamblin, Magovern, and Bessler. Applicants

have amended independent claims 1, 20, and 45. The Examiner's rejections are respectfully traversed.

Applicants' invention, as limited by independent claims 1 and 20, relates to an artificial valve attachment with a unidirectional valve, a connector band attached circumferentially around said valve, and a plurality of fingers oriented in a direction substantially parallel to the direction of blood flow and attached around the band. Independent claim 45 relates to an embodiment of the invention that does not require a band. Claim 45 includes a unidirectional valve, and a plurality of fingers oriented in a direction substantially parallel to the direction of blood flow. The fingers in claim 45 are attached circumferentially around the valve.

Hamblin

The Examiner asserted that Hamblin teaches a heart valve comprising a valve portion, a connector band (12), and a plurality of fingers (50) and that applicants' invention is anticipated by Hamblin. Applicants have amended claims 1, 20, and 45 to limit the invention to embodiments of artificial heart valve attachments with fingers oriented substantially parallel to the direction of blood flow, in accordance with the principles of the present invention. Hamblin neither shows nor suggests fingers in a direction substantially parallel to the direction of blood flow.

Instead of fingers oriented substantially parallel to the direction of blood flow, Hamblin shows fingers (referred to as "staples") substantially perpendicular to the direction of blood flow (e.g., see Hamblin, FIGS. 4 and 5). Hamblin's staples are bent (e.g., see Hamblin, FIG 3, 4, and 5) such that a first end and a second end of each staple form a pair of fingers that oppose one and other (e.g., see Hamblin, claims 20, 30 and 31). Hamblin further describes the opposing ends or fingers as being configured to define an opening, having several different geometric configurations (e.g., a triangular, rectangular or semi-circular opening), for surrounding a patient's heart tissue (e.g., see Hamblin, column 3, lines 32-40). This description, in view of FIGS. 3-5, indicates that the staples in Hamblin are substantially perpendicular to the direction of blood flow.

Therefore, at least because Hamblin neither shows nor suggests fingers oriented substantially parallel to the direction of blood flow, applicants' invention is not anticipated by Hamblin. The Examiner's rejection under 35 U.S.C. § 102(e), based on Hamblin, is respectfully traversed.

Magovern

The Examiner asserted that Magovern teaches a heart valve comprising a valve portion, a connector band (2), and a plurality of fingers (20) and that applicants' invention is anticipated by Magovern. Applicants have amended claims 1, 20, and 45 to limit the invention to embodiments of artificial heart valve attachments with fingers oriented substantially parallel to the direction of blood flow, in accordance with the principles of the present invention. Magovern neither shows nor suggests fingers in a direction substantially parallel to the direction of blood flow as claimed by applicants.

Instead of fingers oriented substantially parallel to the direction of blood flow, Magovern relates to fingers oriented in a direction substantially perpendicular to the direction of blood flow. Specifically, Magovern teaches radially oriented pins or needles for the purpose of tissue attachment (e.g., see Magovern claim 1). In FIG. 1 of Magovern, axial passageway 8 is defined by annular ring 2 (e.g., see Magovern, paragraph beginning at column 2, line 66), thereby determining the direction of blood flow as being substantially axial. Therefore, because the axial direction of a ring is perpendicular to the radial direction of a ring and Magovern only teaches radially extending pins, Magovern teaches a heart valve with fingers or pins oriented

in a direction substantially perpendicular to the direction of blood flow.

Therefore, at least because Magovern does not relate to an artificial heart valve with a plurality of fingers substantially parallel to the direction of blood flow, applicants' invention is not anticipated by Magovern. The Examiner's rejection under 35 U.S.C. § 102(e), based on Magovern, is respectfully traversed.

Bessler

The Examiner asserted that Bessler teaches a heart valve comprising a valve portion, a connector band (2), and a plurality of fingers (20) and that applicants' invention is anticipated by Hamblin. However, Bessler does not claim a plurality of fingers oriented substantially parallel to the direction of blood flow as claimed by applicants.

The Examiner asserted that element 20 in Bessler refers to a plurality of fingers. According to Bessler (e.g., see column five, line 18), element 20 is an artificial heart valve. Applicants respectfully submit that the Examiner misread Bessler with respect to element 20.

Therefore, at least because Bessler does not claim a plurality of fingers oriented substantially parallel to the direction of blood flow, applicants' invention is not anticipated by Bessler. The Examiner's rejection under 35

U.S.C. § 102(e), based on Bessler, is respectfully traversed.



Conclusion

In view of the forgoing, claims 1, 3-5, 7, 9, 20, 23-25, 27, 29, 45-49, and 53 are in condition for allowance. Accordingly, prompt reconsideration is respectfully requested.

Respectfully submitted,

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Appendix

Showing the Changes in the Claims

1. (Amended) A valve apparatus for deploying in, and securing to, a tissue annulus, said valve comprising:

a uni-directional valve portion for passing fluid in one direction and obstructing fluid in an opposite direction;

a connector band located circumferentially around, and attached to, said valve portion; and

a plurality of fingers located circumferentially around, and attached to, said band, said fingers being oriented substantially parallel to the direction of blood flow and adapted to secure said valve to said tissue annulus.

20. (Amended) A connector band for providing an interface between a uni-directional valve and a tissue annulus, said band comprising:

a wall for location circumferentially around, and attachment to, said valve, said wall [having a plurality of recesses] for receiving said valve; and

a plurality of fingers located circumferentially around, and attached to, said wall, said fingers being oriented substantially parallel to the direction of blood flow and adapted to secure said band to said tissue annulus.

45. (Amended) A valve apparatus for deploying in, and securing to, a tissue annulus, said valve comprising:

a uni-directional valve portion for passing fluid in one direction and obstructing fluid in an opposite direction; and

a plurality of fingers located circumferentially around, and attached to, said valve, said fingers being oriented substantially parallel to the direction of blood flow and adapted to secure said valve to said tissue annulus.